UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge Honorable Joel Schneider, Magistrate Judge
This Document Relates to All Actions	

DEFENDANTS' POSITION STATEMENT FOR JUNE 26, 2019 CASE MANAGEMENT CONFERENCE

The Defendants hereby submit their position statements with respect to the topics on the joint agenda for the June 26, 2019 Case Management Conference.

1. Discovery Confidentiality Order

The parties held a telephonic status conference with the Court on Thursday, June 20 to resolve the sole remaining issue in dispute regarding the Discovery Confidentiality Order ("DCO"), which pertained to paragraph 29 and the applicability of confidentiality to documents shown in third-party depositions. Defendants incorporated the Court's language as instructed into paragraph 29 of the DCO and circulated to Plaintiffs on Friday, June 21 with a request for approval to file with the Court. Defendants are awaiting approval from Plaintiffs to submit the final DCO for execution and entry by the Court.

2. Status of Short Form Complaint

Defendants provided Plaintiffs a redlined draft of the Short Form Complaint on June 14, 2019. Defendants' revisions in large part supplemented the initial draft with sections utilized in the *Benicar* Short Form Complaint that Plaintiffs had not included in their initial draft. Plaintiffs responded with edits to Defendants' redlines on Friday, June 21. The parties conferred by telephone on Monday, June 24, and we continue to work to reach agreement to the extent possible. The parties anticipate addressing any irreconcilable disputes regarding the Short Form Complaint at the next discovery teleconference on July 10.

3. Status of Plaintiff Fact Sheets

Defendants provided a combined draft Plaintiff's Fact Sheet for personal injury claimants and consumer class representatives to Plaintiffs on June 14, 2019. On June 19, Defendants sent Plaintiffs a draft Plaintiff's Fact Sheet for third party payor entities. Defendants are awaiting Plaintiffs' response to the proposed drafts. Plaintiffs have agreed to provide their response to

Defendants during the week of June 24. We anticipate being able to identify any key disputes at the next discovery teleconference on July 10, with the goal of finalizing the Plaintiff's Fact Sheets at or before of the July 24 Case Management Conference.

4. Status of Stipulated Dismissal Process

Defendants provided Plaintiffs with a proposed Defendant Dismissal Form on June 16, 2019, and followed up with Plaintiffs via email on June 20, 2019. Defendants are awaiting Plaintiffs' response to the proposed draft.

5. Coordination of Non-MDL Matters

As discussed in greater detail in the Agenda for May 29, 2019 Case Management Conference, *see* ECF 107 at 9–10, there are currently six valsartan-related actions pending outside the MDL. Brief updates related to these actions are provided below:

- *Runo v. Prinston Pharmaceutical Inc.*, No. MID-L-00856-19 (N.J. Super.) and *Orlowsky v. Solco Healthcare U.S., LLC*, No. MID-L-0002554-19 (N.J. Super.):

  Presiding Judge Jamie D. Happas of Middlesex County, New Jersey has denied the request to consolidate these two actions. Judge Happas has also scheduled a case management conference for July 18, 2019, which counsel from both *Runo* and *Orlowsky* have been ordered to attend. Should the Court wish to speak with Judge Happas, her telephone number is (732) 645-4300 ext. 88376.

- *Robertson v. Prinston*, No. MID-L-004228-19 (N.J. Super.):

  Robertson has been assigned to Judge Patrick Bradshaw, whose telephone number is (732) 645-4300 ext. 88261.[1]

- *Shanov v. Walgreens Co.*, No. 2018-CG-15272 (Cook Co. Cir. Ct., Illinois):

  There are no further developments in this case.

- *Collins v. Prinston Pharmaceutical Inc.*, No. 3:19-cv-00415 (S.D. Cal.) and *Collins v. Aurobindo Pharma USA, Inc.*, No. 3:19-cv-0688 (S.D. Cal.):

  The JPML will consider Plaintiff Carrie Collins's motions to vacate transfer of these two valsartan actions to the MDL at its July 25, 2019 hearing.

[1] A chart containing contact information for all other judges can be found at ECF 107, Exhibit A.

6. Inclusion of Losartan and Irbesartan in the MDL

Plaintiffs have informed Defendants that they intend to petition the JPML, for hearing at its September conference, to expand the scope of the MDL to include losartan and irbesartan. Without seeing the content and scope of the petition, Defendants are unable to make a final decision on whether they would join or oppose expansion. If Plaintiffs' petition is sufficiently narrow in scope (*i.e.*, it does not alter or expand the allegations in the Valsartan Master Complaints), it is likely many Defendants may not oppose the inclusion of losartan and irbesartan in this MDL. Defendants reserve any final decision in this regard until Plaintiffs provide Defendants a draft of the petition.

7. Master Complaints/Process for Motions to Dismiss

On June 17, Plaintiffs filed three Master Complaints against each of the 41 Defendants heretofore named as a Defendant in one of the actions previously transferred to the MDL, as well as certain new Defendants.[2] In their Consolidated Amended Economic Loss Class Action Complaint, a putative class of consumers and a putative class of third party payors ("TPPs") assert eighteen causes of action, including, but not limited to, breach of express and implied warranties, fraud, negligence, violations of state consumer protection laws, and unjust enrichment. All of those economic claims are generally predicated on the theory that Defendants misrepresented the quality, nature, and characteristics of the valsartan containing drugs ("VCDs") that they sold to consumers, and for which TPPs paid, because of an alleged impurity contained in those VCDs. Plaintiffs' Master Personal Injury Complaint asserts strict liability, negligence, wrongful death, and punitive damages claims, among others. All of those bodily injury claims are generally predicated on the theory that certain plaintiffs who consumed VCDs experienced physical injury or death as a result of consuming VCDs allegedly containing an impurity. In their Consolidated Amended Medical Monitoring Class Action Complaint, a putative class of plaintiffs allege having experienced genetic or cellular damage and/or increased risk of cancer due to ingesting Defendants' VCDs allegedly containing an impurity, and repeat many of the claims asserted in the other two Master Complaints.

Defendants are still in the process of reviewing and evaluating the Master Complaints, which contain approximately 1,700 total allegations over approximately 400 pages. However, even upon initial review, Defendants have identified several deficiencies in the Master Complaints that warrant dismissal of certain claims and/or Defendants under F.R.C.P. 12(b). Such dismissals would materially narrow the scope of each type of action and thus enhance the efficiency of this MDL.

For example, the economic loss claims, because they are not based on any physical injury experienced by any class member, are subject to dismissal in their entirety for lack of standing under Article III. *See In re Johnson and Johnson Talcum Powder Prod. Mktg., Sales Practices*

[2] For example, Plaintiffs for the first time name Express Scripts, Inc., Express Scripts Holding Company, Cigna Corporation, OptumRX, Optum, Inc, UnitedHealth Group, Albertsons Companies, LLC, Humana Pharmacy, Inc., Humana, Inc., McKesson Corp., and AmerisourceBergen Corporation as Defendants. *See* ECF 122 at ¶¶ 97-131.

& Liab. Litig, 903 F.3d 278, 281 (3d Cir. 2018) ("buyer's remorse, without more, is not a cognizable injury under Article III of the United States Constitution"). In fact, the FDA recognized that the VCDs at issue were still effective treatments and directed patients to continue taking their medication.[3] Thus, the alleged class members received the benefit of the VCD they paid for.

Also, a number of the state law claims raised in both the economic loss and personal injury complaints are preempted by federal law. When federal law prohibits an action that state law requires, "the state law is without effect." *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 570 U.S. 472 (2013). Here, the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq., and FDA regulations create strict statutory obligations for generic drug manufacturers, including that generic drugs have "the same active ingredients, route of administration, dosage form, strength, and labeling" as their equivalent brand-name counterparts. *Bartlett*, 570 U.S. at 477. The "duty of sameness" prohibits recovery under state law for allegedly defective generic drug labeling and for failure to disseminate additional information concerning enhanced warnings. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 616-619 (2011); *see also Moore v. Zydus Pharms. (USA), Inc.*, 277 F. Supp. 3d 873, 878 (E.D. Ky. 2017) (under federal law, ANDA holders "cannot disseminate additional information . . . or directly correspond with healthcare providers concerning enhanced warnings[.]"). Preemption will therefore eliminate many of the state-law claims, including, for example, breach of express and implied warranty, fraud, failure-to-warn, negligent misrepresentation, strict liability based on design defect, and violation of consumer protection statutes. *See, e.g., In re Fosamax (Alendronate Sodium) Products Liability Litigation (No. II)*, 2011 WL 5903623 (D. N.J. Nov. 21, 2011) (dismissing state law claims as preempted); *Morris v. PLIVA, Inc*., 713 F. 3d 774, 777 (5th Cir. 2013) (same).

Additionally, Defendants that qualify as "innocent sellers"—such as retailers—are entitled to dismissal from products litigation under the laws of many states. *See, e.g.,* N.J. Stat. § 2A:58C-9; COLO. REV. STAT. § 13-21-402(1); DEL. CODE tit. 18, § 7001; KAN. STAT. § 60-3306; KY. REV. STAT. § 411.340; MD. CODE [CTS. & JUD. PROC.] § 5-405; MINN. STAT. § 544.41; MISS. CODE § 11-1-63(g-h); MO. REV. STAT. § 537.762(1). For example, New Jersey's innocent seller statute entitles "a product seller" to dismissal if the seller "file[s] an affidavit certifying the correct identity of the manufacturer of the product which allegedly caused the injury, death or damage." N.J. Stat. § 2A:58C-9(a).

While Defendants are in the process of assessing the Master Complaints, which were only just received on Monday, June 17, the above examples demonstrate that motion practice under Rule 12(b) is warranted. Nevertheless, Defendants are mindful that the Court would prefer that such motions raise only material defects that are incurable from a pleading standpoint and that would have a meaningful impact on the scope of these proceedings. Accordingly, Defendants suggest a process whereby the parties would first meet and confer about the Rule 12(b) issues Defendants might raise with the Court to determine if and how any may be resolved

[3] *See* "FDA Statement on the FDA's ongoing investigation into valsartan and ARB class impurities and the agency's steps to address the root causes of the safety issues," (Jan. 15, 2019), *available at* https://www.fda.gov/news-events/press-announcements/fda-statement-fdas-ongoing-investigation-valsartan-and-arb-c`lass-impurities-and-agencys-steps.

without the Court's assistance, and then, upon the Court's direction regarding a briefing schedule, Defendants would brief any Rule 12(b) issues on which the parties could not agree.

Defendants propose that the meet and confer process begin with a letter from Defendants to Plaintiffs setting forth the Rule 12(b) issues Defendants believe should be addressed, followed with a responsive letter from Plaintiffs, a short period for meeting and conferring on the parties' differences, and then a report to the Court outlining the issues that were resolved as well as those that are ripe for briefing so that a briefing schedule may be established. Plaintiffs have declined Defendants' invitation to discuss a process for such motion practice.

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/s/ *Seth A. Goldberg*

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